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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/042,016  | 01/10/2002  | David L. Rimm        | H-1296(4)           | 5330             |
| 7590 12/02/2004   |             |                      | EXAMINER            |                  |
| William W. Jones<br>6 Juniper Lane<br>Madison, CT 06443 |             |                      | CHIN, CHRISTOPHER L |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1641                |                  |

DATE MAILED: 12/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |  |                                    |  |
|------------------------------|--|------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/042,016   | <b>Applicant(s)</b><br>RIMM ET AL. |  |
|                              | <b>Examiner</b><br>Christopher L. Chin | <b>Art Unit</b><br>1641            |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 September 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 4-8 and 11-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 10 and 14 is/are rejected.
- 7) ☒ Claim(s) 2, 3, 9, 15 and 16 is/are objected to.
- 8) ☒ Claim(s) 1-16 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Group I – claims 1-10 and 14-16 in the reply filed on 9/20/04 is acknowledged.

Applicant's election of HIV-1 in claim 3 for the election of species is also acknowledged.

Claims 4-8 and 11-13 are withdrawn from consideration as being drawn to non-elected claims.

### ***Specification***

2. The disclosure is objected to because of the following informalities:  
a.) The status of the parent application cited on page 1 of the specification needs to be updated.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

3. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 is vague. The recitation of "said well-defined free volume" lacks antecedent support.

### ***Double Patenting***

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1 and 14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,197,523. Although the conflicting claims are not identical, they are not patentably distinct from each other because patent '523 claims a method with essentially the same steps as the instantly claimed invention.

Patent '523 claims:

A method for detecting the presence or absence of individual circulating epithelial cancer cells in an anticoagulated whole blood sample, said method comprising the steps of:

a) providing a transparent container having a cavity containing an insert, said container and insert combining to form a free volume between the insert and the walls of the container;

b) combining the blood sample with one or more epitope-specific labeling agents so as to differentiate any individual epithelial cancer cells from other cells in the blood sample;

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c) combining the blood sample with a colorant which is operable to clarify individual epithelial cancer cell morphology in all individual epithelial cancer cells in the blood sample;

d) placing the blood sample in the container and centrifuging the blood sample in the container so as to cause any individual epithelial cancer cells present in the blood sample to localize in said free volume in the container;

e) enumerating any individual differentiated epithelial cancer cells found in situ in the free volume in the container;

f) examining the cell morphology of any individual differentiated epithelial cancer cells in situ in the free volume in the container;

g) said combining steps being performed either before or after the blood sample is placed in the container; and

h) said enumerating and examining steps being performed in no particular order.

The method in patent '523 differs from the instant invention in specifying detection of circulating epithelial cancer cells in an anticoagulated whole blood sample while the instant invention recites analyzing an anticoagulated whole blood sample for the presence or absence of target circulating blood cells.

However, it would have been obvious to one of ordinary skill in the art that the recitation of "target circulating blood cells" in the instant invention broadly encompasses the "circulating epithelial cancer cells" in the '523 patent.

### ***Allowable Subject Matter***

6. Claims 2, 3, 9, and 15-16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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7. Claim 10 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

### ***Conclusion***

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The following U.S. Patents disclose a test device comprising a container with an insert

5,321,975; 5,342,790; 5,460,979; 5,635,362; 5,723,285; 5,830,639; 5,759,794; 5,776,710; and 5,834,217.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher L. Chin whose telephone number is (571) 272-0815. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Christopher L. Chin  
Primary Examiner  
Art Unit 1641

11/19/04